

REMARKS

Summary of Office Action

Claims 46-48, 50-61, 64-74, 76 and 77 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO/2003/039505, cited in the instant Office Action as the alleged English equivalent, Bankowski et al., U.S. Patent No. 7,294,330 (hereafter "BANKOWSKI").

Claims 62 and 63 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BANKOWSKI in view of US Patent Publication 2002/0077372 (hereafter "GERS").

Claims 46-48, 50-56, 64-70, 72-74, 76 and 77 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shen, U.S. Patent No. 6,042,816 (hereafter "SHEN"), in view of Yu et al., U.S. Patent No. 5,571,841 (hereafter "YU").

Claims 57-63 and 71 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over SHEN in view of YU in further view of GERS.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are again respectfully requested, in view of the following remarks.

Response to Rejections of Claims under 35 U.S.C. § 103(a) over BANKOWSKI as Primary Document

Claims 46-48, 50-61, 64-74, 76 and 77 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BANKOWSKI, and claims 62 and 63 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BANKOWSKI in view of GERS. The rejections repeat the allegations set forth in the previous Office Action and essentially allege that with the exception

of claims 62 and 63 the elements of the rejected claims are either disclosed or rendered obvious by BANKOWSKI and that the elements recited in claims 62 and 63 are rendered obvious by GERS. The Examiner again concedes that BANKOWSKI fails to disclose "an example wherein the claimed components, at the claimed percentages are combined into a single composition" but alleges that BANKOWSKI teaches "that all of the claimed components may be combined into a composition within the claimed percentage ranges".

Applicants respectfully traverse these rejections for all of the reasons which are set forth in the response to the previous Office Action. The corresponding remarks are expressly incorporated herein.

It further is pointed out again that BANKOWSKI teaches hundreds, if not thousands, of substances which are suitable as β -glucuronidase-inhibiting substances. In particular, in col. 2, lines 8-65 thereof BANKOWSKI states (emphasis added):

The present invention relates to the non-therapeutic use of at least one .beta.-glucuronidase-inhibiting substance chosen from monobasic mono- α -hydroxycarboxylic acids having 2-6 carbon atoms and their physiologically acceptable salts, monobasic polyhydroxycarboxylic acids having 4-8 carbon atoms and 3-7 hydroxyl groups, their intramolecular condensation products as well as ethers thereof with mono-, oligo- and polysaccharides or esters thereof with organic and with inorganic acids as well as the physiologically acceptable salts of these components, polybasic carboxylic acids which are not hydroxy-substituted and have 3-8 carbon atoms and 2-3 carboxyl groups, their esters with optionally alkyl-substituted mono- and oligosaccharides as well as the physiologically acceptable salts of these components, polybasic monohydroxycarboxylic acids having 4-8 carbon atoms and 2-3 carboxyl groups, their esters with optionally alkyl-substituted mono- and oligosaccharides as well as the physiologically acceptable salts of these components, polybasic polyhydroxycarboxylic acids having 4-8 carbon atoms, 2-6 hydroxyl groups and 2-3 carboxyl groups, their esters with optionally alkyl-substituted mono- and oligosaccharides as well as the physiologically acceptable salts of these components, aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group, as well as physiologically acceptable salts thereof, amino acids as well as physiologically acceptable salts thereof, 6,7-disubstituted 2,2-dialkylchromanes or -chromenes, phenolic glycosides with a phenoxy radical substituted at least in the para-position, wherein the substituents are chosen from a methoxy, ethoxy, isopropoxy, n-propoxy, vinyl, methylvinyl, 1-propenyl, 2-propenyl

(allyl), isobutenyl, methyl, ethyl, n-propyl, isopropyl, n-butyl, isobutyl, tert-butyl, ketopropyl, β -ketobutyl, γ -ketobutyl, β -ketopentyl, γ -ketopentyl and a δ -ketopentyl radical, flavonoids, isoflavonoids, polyphenols, the extracts from green tea (*Camellia sinensis*), from Paraguayan tea (*Ilex paraguayensis*), from Japanese tea (*Camellia japonensis*), from the fruits (berries) of the fan palm or saw palm (*Saw Palmetto*, *Serenoa repens*), from the leaves of Ginkgo biloba, from apple pips, from the fruits (berries) of *Phyllanthus emblica*, from the leaves of the olive tree (*Olea europaea*), from the bark of the pine tree (*Pinus Pinaster*), from rosemary, from *Bacopa Monniera*, from willow-herb, hyssop, clove, from the blue alga *Spirulina platensis* which has been enriched with magnesium, and from yeast, monocyclic hydrocarbon compounds having 6-12 carbon atoms, 1-2 hydroxyl groups and oxygen atoms as the only heteroatoms, wherein the ring is formed from 6 or 7 atoms and can be saturated, unsaturated or aromatic, derivatives of phosphonic acid and phosphoric acid chosen from hydroxyethane-1,1-diphosphonic acid, diethylenetriaminepenta (methylenephosphonic acid), myo-inositol-hexaphosphoric acid (phytic acid) and phosphonomethylated chitosan as well as the alkali metal salts of these components, zinc ricinoleate, geraniol-7 EO as well as soluble inorganic salts of copper(II), zinc and magnesium, in a cosmetic deodorant or antiperspirant composition for reducing the body odor caused by hydrolytic decomposition of steroid esters.

Virtually each of the most diverse classes of compounds mentioned above is discussed in the passage from col. 2, line 66 to col. 9, line 32 of BANKOWSKI.

Regarding the aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group BANKOWSKI states in the passage from col. 4, line 61 to col. 5, line 9 thereof (emphasis added):

The aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group which are preferred according to the invention and derivatives thereof include mandelic acid, para-hydroxymandelic acid, rosemary acid, ferulic acid, chlorogenic acid, salicylic acid, 2,3-dihydroxybenzoic acid (pyrocatechuic acid), 2,4-dihydroxybenzoic acid β -resorcylic acid), 2,5-dihydroxybenzoic acid (gentisic acid), 2,6-dihydroxybenzoic acid γ -resorcylic acid), 3,4-dihydroxybenzoic acid (protocatechuic acid), 3,5-dihydroxybenzoic acid (α -resorcylic acid), gallic acid, the methyl, ethyl isopropyl, propyl, butyl, hexyl, ethylhexyl, octyl, decyl, ethyloctyl, cetyl and stearyl esters and the alkali metal salts of these carboxylic acids. Rosemary acid, ferulic acid and para-hydroxymandelic acid sodium salt are particularly preferred.

Further, BANKOWSKI discloses that cosmetic deodorant compositions which contain a selected β -glucuronidase-inhibiting substance may contain various other, non-essential components

such as the hundreds of fat substances, non-polar or polar liquid oils, water-soluble alcohols, hydrophilically modified silicones, surface-active substances, lipophilic coemulsifiers, antiperspirant active compounds and additional deodorants (fragrances, antimicrobial, antibacterial or germ-inhibiting substances, antioxidants or odor absorbents), complexing substances, thickeners and further cosmetically and dermatologically active substances, as disclosed in the passage from col. 10, line 56 to col. 18, line 6 (spanning about 8 columns), of BANKOWSKI.

Accordingly, BANKOWSKI encompasses thousands, if not millions, of possible combinations of (i) β -glucuronidase-inhibiting substances and (ii) non-essential components. In view thereof it is not seen that BANKOWSKI teaches a “reasonable number of embodiments which are only directed to deodorant and antiperspirant formulations” as alleged at page 16 of the instant Office Action, and neither is it seen that BANKOWSKI would have prompted one of ordinary skill in the art to provide a composition which comprises both mandelic acid (as β -glucuronidase-inhibiting substance) and an aluminum compound and in particular, an activated aluminum compound as antiperspirant, let alone in the ratios recited in the instant independent claims.

In the latter respect it is noted that at page 16 of the instant Office Action the Examiner takes the position that “said ratios are found within the preferred ranges of [BANKOWSKI] delineated above”.

Applicants submit that the most preferred range for the concentration of the (host of) antiperspirant active compounds set forth in col. 15, lines 35-51 of BANKOWSKI is 10-25 wt. % (col. 5, lines 54-58 of BANKOWSKI) and the most preferred range for the concentration of aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group is 0.008 % to 2 wt. % (col. 5, lines 10-15 of BANKOWSKI), which can be calculated

to result in a ratio corresponding to (a) : (b) as recited in the instant claims of 25 : 0.008 to 10 : 2, i.e., from about 3,000 : 1 to 5 : 1 (spanning 3 orders of magnitude). In view thereof, it is not surprising that the range of ratios (a) : (b) recited in the instant claims (e.g., from 15 : 1 to 1 : 1 in claim 46) is (partially) encompassed by the corresponding range that can be calculated on the basis of the most preferred concentration ranges of the individual components taught by BANKOWSKI.

In this regard, it further is noted that three of the exemplified compositions of BANKOWSKI contain aluminum chlorohydrate (not indicated to be activated) and an aromatic carboxylic acid having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group, i.e., the sprayable translucent antiperspirant microemulsion 2.7 (containing 8 wt.% of aluminum chlorohydrate and 0.01 wt.% of rosemary acid, resulting in a ratio corresponding to (a) : (b) of 800 : 1) and two of the antiperspirant roll-ons shown in the second table in col. 23 of BANKOWSKI (each of them containing 20 wt.% of aluminum chlorohydrate and about 0.5 wt.% of p-hydroxymandelic acid sodium salt or 0.4 wt.% of salicylic acid, resulting in ratios corresponding to (a) : (b) as recited in the instant claims of about 40:1 and 50:1, respectively).

Accordingly, the only exemplified compositions of BANKOWSKI which contain aluminum chlorohydrate (not indicated to be activated) and an aromatic carboxylic acid having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group (all different from mandelic acid) show ratios corresponding to (a) : (b) as recited in the instant claims which are far outside the claimed range (by a factor of at least 2.7). This is yet another reason why BANKOWSKI is unable to render obvious the subject matter of any of the instant claims.

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the response to the previous Office Action, the instant rejection under 35 U.S.C. § 103(a)

over BANKOWSKI and the rejection under 35 U.S.C. § 103(a) over BANKOWSKI and GERS are without merit, wherefore withdrawal thereof is again respectfully requested.

Response to Rejections of Claims under 35 U.S.C. § 103(a) over SHEN as Primary Document

Claims 46-48, 50-56, 64-70, 72-74, 76 and 77 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over SHEN in view of YU and claims 57-63 and 71 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over SHEN in view of YU in further view of GERS. The rejections essentially repeat the allegations set forth in the previous Office Action and assert, *inter alia*, that SHEN teaches compositions comprising enhanced antiperspirant salts, which allegedly reads on activated antiperspirants, alpha-hydroxycarboxylic acids, and water.

The Examiner concedes that SHEN does not teach mandelic acid as hydroxycarboxylic acid but alleges that YU cures this deficiency of SHEN. In this regard, the rejection essentially asserts that YU would have rendered it obvious to one of ordinary skill in the art to produce the formulations of SHEN with mandelic acid as hydroxycarboxylic acid. One of ordinary skill in the art would allegedly have been motivated to do so “because [SHEN] teaches antiperspirant compositions comprising hydroxycarboxylic acids and [YU] teach[es] that alpha-hydroxycarboxylic acids, such as mandelic acid, may be added to antiperspirant formulations to increase efficacy and to reduce wrinkles”. Page 10, next-to-last paragraph of instant Office Action.

Applicants respectfully traverse these rejections for all of the reasons which are set forth in the responses to the previous Office Actions. The corresponding remarks are expressly incorporated herein.

It further is pointed out again that the hydroxycarboxylic acids which are to be employed according to SHEN are hydroxy substituted lower alkanolic acids, preferably alkanolic acids having from 2 to 4 carbon atoms in the alkanolic acid chain. This clearly excludes araliphatic acids such as mandelic acid (having a total of 8 carbon atoms). In particular, the passage of SHEN relied on by the Examiner in this regard, col. 6, lines 45-62, states (emphasis added):

The compositions of the present invention also contain a water soluble amino and/or hydroxy acid which is effective in increasing and/or stabilizing the HPLC peak 4:3 area ratio of the antiperspirant salt. Such acids include amino-and/or hydroxy-substituted lower alkanolic acids (including substituted derivatives thereof), preferably where the amino or hydroxy group is located on the α -carbon (i.e. the same carbon to which the carboxy group is attached). The lower alkanolic acid will generally have 2 to 6, preferably 2 to 4, carbon atoms in the alkanolic acid chain. Typical amino and/or hydroxy substituted lower alkanolic acids include any of the amino acids such as glycine, alanine, valine, etc. and hydroxy acids such as glycolic acid and lactic acid. These amino and/or hydroxy substituted lower alkanolic acids may also contain various substituents which do not adversely affect their activity. The preferred amino and/or hydroxy substituted lower alkanolic acids are glycine, alanine, and glycolic acid, with glycine being most preferred.

Applicants note that the only hydroxy substituted lower alkanolic acids having 2 to 6 carbon atoms in the alkanolic acid chain mentioned in the passage of SHEN reproduced above are glycolic acid and lactic acid, i.e., acids having 2 or 3 carbon atoms. The impression that acids with an as low as possible number of carbon atoms are (highly) preferred according to SHEN is reinforced by the fact that the above passage further teaches that glycine (2 carbon atoms) and alanine (3 carbon atoms) are the preferred amino acids, with glycine being the most preferred acid among the amino and/or hydroxy substituted lower alkanolic acids taught by SHEN.

It is submitted that in view of the foregoing facts it cannot reasonably be alleged that SHEN prompts one of ordinary skill in the art to use as amino and/or hydroxy substituted lower alkanolic acid an acid which not only is not a (lower) alkanolic acid (as preferred according to SHEN) but also

contains significantly more carbon atoms (e.g., eight carbon atoms) than the acids which SHEN indicates to be (particularly) preferred.

YU is unable to cure the noted deficiency of SHEN. In particular, even though YU teaches that the hydroxycarboxylic acids disclosed therein may enhance the therapeutic efficacy of cosmetic or pharmaceutical agents of topically applied agents such as, *inter alia*, antiperspirants, it must not be forgotten that according to YU hundreds, if not thousands of hydroxycarboxylic acids are suitable for this purpose.

It further is pointed out that glycolic acid and lactic acid, i.e., the two hydroxy-substituted lower alkanolic acids that are most preferred according to SHEN, are not only mentioned in YU as representatives of the hydroxycarboxylic acids taught therein, but are even employed in several of the Examples thereof (see, e.g., Examples 6, 7, 8, 15, 19, 20, 26, and 27 of YU).

In contrast, mandelic acid, while also is mentioned in YU as an example of a suitable hydroxycarboxylic acid, is not employed in any of the 29 Examples of YU. Accordingly, even if one of ordinary skill in the art wanted to increase the efficacy of the antiperspirant compositions of SHEN by using a hydroxycarboxylic acid according to YU, there would be no reason to deviate from the teaching of SHEN and to use a hydroxycarboxylic acid which is significantly different from the hydroxycarboxylic acids which are apparently most suitable for the purposes of SHEN. In particular, a comparison of the teachings of SHEN and YU clearly suggests that the hydroxy-substituted lower alkanolic acids which are most preferred according to SHEN would also have the desired efficacy-improving effect taught by YU. In other words, also YU is unable to prompt one of ordinary skill in the art to use mandelic acid instead of glycolic acid or lactic acid as hydroxy-substituted lower alkanolic acid in the compositions of SHEN.

Applicants further note that even if one were to assume, *arguendo*, that YU emphasizes mandelic acid as particularly suitable for treating wrinkles (although it is not seen that the specification of YU provides any support for this allegation or that YU even only mentions this alleged property of mandelic acid anywhere other than in the title and in the claims thereof), it is apparent that the ability of a composition to visibly reduce human skin wrinkles (in the axillia) provides no particularly noteworthy benefit for an antiperspirant composition and is clearly not able to outweigh the fact that the hydroxy-substituted lower alkanolic acids which SHEN teaches to be most preferred for the purposes disclosed therein are significantly different from mandelic acid (not taking into account the fact that the most preferred acid for the purposes of SHEN is not even a hydroxy-substituted lower alkanolic acid but an amino acid, i.e., glycine, the member of this class of compounds with the smallest number of carbon atoms).

It further is emphasized again that SHEN requires the use of a soluble calcium salt (see, e.g., claim 1 of SHEN) and that from, e.g.,
http://books.google.com/books?id=Owuv-c9L_IMC&pg=PA618&lpg=PA618&dq=soluble+%22calcium+mandelate%22&source=bl&ots=zVs_siTcb&sig=icChVCOYa24E3XvLMZx1OVO7L9c&hl=en&ei=gi44Sue9F9CptgeA3tXiDA&sa=X&oi=book_result&ct=result&resnum=3

it can be taken that calcium mandelate is only slightly soluble in water, which clearly is a disincentive rather than a motivation to use mandelic acid for the purpose disclosed in SHEN and is yet another reason why one of ordinary skill in the art would not (be prompted to) use mandelic acid as hydroxycarboxylic acid in the stabilization process disclosed by SHEN.

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the responses to the previous Office Actions, SHIN in view of YU (and GERS) fails to render obvious the subject matter of any of the claims submitted herewith. In view thereof, withdrawal of the instant rejection under 35 U.S.C. § 103(a) over SHEN in view of YU and the rejection under 35 U.S.C. § 103(a) over SHEN in view of YU and GERS is clearly warranted as well and thus respectfully requested.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, wherefore an early issuance of the Notices of Allowance and Allowability is again respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
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